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Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial: A description of the severity and extent of disease using the Bollinger angiogram scoring method and the TransAtlantic Inter-Society Consensus II classification

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Background: **The Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial showed in patients with severe lower limb ischemia (rest pain, tissue loss) who survive for 2 years after intervention that initial randomization to bypass surgery, compared with balloon angioplasty, was associated with an improvement in subsequent amputation-free survival and overall survival of about 6 and 7 months, respectively. The aim of this report is to describe the angiographic severity and extent of infrainguinal arterial disease in the BASIL trial cohort so that the trial outcomes can be appropriately generalized to other patient cohorts with similar anatomic (angiographic) patterns of disease.**

Methods: **Preintervention angiograms were scored using the Bollinger method and the TransAtlantic Inter-Society Consensus (TASC) II classification system by three consultant interventional radiologists and two consultant vascular surgeons unaware of the treatment received or patient outcomes.**

Results: **As was to be expected from the randomization process, patients in the two trial arms were well matched in terms of angiographic severity and extent of disease as documented by Bollinger and TASC II. In patients with the least overall disease, it tended to be concentrated in the superficial femoral and popliteal arteries, which were the commonest sites of disease overall. The below knee arteries became increasingly involved as the overall severity of disease increased, but the disease in the above knee arteries did not tend to worsen. The posterior tibial artery was the most diseased crural artery, whereas the peroneal appeared relatively spared. There was less interobserver disagreement with the Bollinger method than with the TASC II classification system, which also appears inherently less sensitive to clinically important differences in infrapopliteal disease among patients with severe leg ischemia.**

Conclusions: **Anatomic (angiographic) disease description in patients with severe leg ischemia requires a reproducible scoring system that is sensitive to differences in crural artery disease. The Bollinger system appears well suited for this purpose, but the TASC II classification system less so. We hope this detailed analysis will facilitate appropriate generalization of the BASIL trial data to other groups of patients affected by similar anatomic (angiographic) patterns of disease. (J Vasc Surg 2010;51:32S-42S.)**

Severe leg ischemia (SLI), characterized by rest/night pain and tissue loss (ulceration, gangrene), leads to significant morbidity and mortality and to the consumption of considerable health and social care resources in developed and developing countries.[1] The Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial remains the only multicenter, randomized controlled trial to have compared a revascularization strategy of bypass surgery (BSX)-first with balloon angioplasty (BAP)-first for the treatment SLI due to infrainguinal disease. An intention-to-treat analysis of the BASIL trial has shown that BSX and BAP lead to similar amputation-free survival (AFS) and overall survival (OS) out to 2 years from randomization.[2] However, for those patients who survived for >2 years after intervention, initial randomization to surgery was associated with a significant increase of 7.3 months in restricted mean OS and a

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*A complete list of the BASIL trial participants is given in the Appendix.

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Competition of interest: The authors had full access to the data and take responsibility for its integrity; read and agree to the manuscript as written; and have no conflict of interest to declare.

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nonsignificant increase of 5.9 months in restricted mean AFS during the subsequent mean follow-up of 3.1 years (range, 1-5.7 years).[3] Hospital costs and health-related quality of life were not significantly different between the two groups during the first 3 years.[4]

These data suggest that SLI patients expected to live >2 years should usually be offered BSX, whereas those not expected to survive >2 years should usually be offered BAP.[5] A "by treatment received" analysis of AFS and OS showed that vein BSX performed significantly better than prosthetic BSX and that BAP performed better than prosthetic BSX. Thus, the BASIL trial outcomes and recommendations need to be considered in the context of the quality of the autogenous conduit available for BSX in each patient.[6]

When designing the BASIL trial, the investigators and participants believed it was important to be able to describe in detail the anatomic (angiographic) severity and extent of disease in randomized patients in order to:

1. establish that the patients in the two arms of the trial were anatomically (angiographically) comparable,
2. facilitate appropriate generalization of the trial data to other groups of SLI patients affected by similar anatomic (angiographic) patterns of disease,
3. examine the relationship between anatomic (angiographic) patterns of disease and outcomes (AFS, OS) for the BASIL cohort as a whole,[5] and
4. examine the relationship between anatomic (angiographic) patterns of disease and outcomes following BSX and BAP.

To these ends, the 27 participating centers were asked to forward copies of preintervention angiograms for independent, blinded, batch analysis at the trial center. In this report we address aims 1 and 2 set out above and present an analysis of those angiograms using the Bollinger scoring method and the TransAtlantic Inter-Society Consensus (TASC) II classification system.[7] The relationship between anatomic (angiographic) patterns of disease and outcomes for the BASIL cohort as a whole (aim 3) has been reported elsewhere,[5] and aim 4 is the subject of on-going further analyses.

METHODS

All patients who participated provided written informed consent, and the study was approved by the Multicentre Research Ethics Committee (MREC) for Scotland. The BASIL trial was registered with the National Research Register (NRR) and the International Standard Randomised Controlled Trials Number (ISRCTN) Scheme (Number 45398889).

Trial design. The BASIL trial methods have been reported in detail previously.[2-4] Briefly, between August 1999 and June 2004, consultant vascular surgeons and interventional radiologists in 27 United Kingdom (UK) hospitals randomized 452 patients with SLI (rest pain or tissue loss, or both) due to infrainguinal disease, and who had a pattern of disease on diagnostic imaging that in their opinion could equally well be treated by BSX or BAP, to a BSX-first or a BAP-first revascularization strategy.

Table I. Bollinger scoring matrix[a]

Severity				
Occlusion	*Stenosis >50%*	*Stenosis 25-49%*	*Plaques <25%*	*Extent of disease*
	4	2	1	Single lesion
13	5	3	2	Multiple lesions affecting less than half the segment
15	6	4	3	Multiple lesions affecting more than half the segment

[a]The vertical columns represent the different severities of atherosclerotic lesions observed. The rows represent the extent of the disease observed in each segment. The additive score for each segment is obtained by adding the scores for the four different categories of severity (please see text for details).

Preintervention angiograms were scored using the Bollinger method and the TASC II classification system by three consultant interventional radiologists and two consultant vascular surgeons unaware of the treatment received or patient outcomes.[5] For the Bollinger method, 13 infrainguinal arterial segments were assessed:[7]

- Profunda femoris artery
- Proximal and distal superficial femoral (Pr-SFA, Di-SFA)
- Proximal (above knee) and distal (below knee) popliteal artery (Pr-PA, Di-PA)
- Tibioperoneal trunk (TPT)
- Proximal (upper half calf) and distal (lower half calf) posterior tibial (Pr-PTA, Di-PTA)
- Proximal and distal anterior tibial artery (Pr-ATA, Di-ATA)
- Proximal and distal peroneal artery (Pr-PerA, Di-PerA)
- Plantar arch

Each of these segments was scored according to the severity and extent of disease (Table I). Four severities of lesion are characterized in the Bollinger method:

- Occlusion of the lumen
- Stenosis ≥50% of the luminal diameter
- Stenosis <50% but >25%, and
- Plaques impinging ≤25% of the diameter

Each type of lesion is further categorized as follows by its extent:

- Single lesion
- Multiple lesions affecting less than half of the segment
- Multiple lesions affecting more than half of the segment

To calculate the additive scores, the individual scores for each of the three lesion severities are summed in accordance with the following rules:

1. In the presence of occlusions, stenoses and plaques are not considered.
2. When both severities of stenoses are present (<50% and >50%), plaques (<25%) are not considered.
3. For each severity of disease, only one extent of disease category is scored.

The plantar arch (where it was included on the angiograms) was scored 0, 4, 6, or 15 according to the degree of stenosis or occlusion present. Not all sites could be scored on all angiograms, because although most angiographic studies included the ankle, forefoot views were often not available.

At the end of randomization, 418 preintervention angiograms were available and considered to be of sufficient quality and completeness to be scorable. These angiograms were sent in batches to two consultant interventional radiologists (observers 1 and 2) who independently scored the angiograms according to the Bollinger method. Observers 1 and 2 did not confer and were unaware of the treatment(s) received by the patients or their outcomes. Overall agreement between observers was good (see Results for details), but there appeared to be material discrepancies in 73 angiograms in respect to one or more arterial segments. These angiogram segments were scored by a panel of two consultant vascular surgeons (observers A and B) and a third consultant interventional radiologist (observer 3). This panel did work together and confer, but they were blind to the scores from observers 1 and 2 and the patients' treatments and outcomes.

In this way, a consensus Bollinger score was obtained for each segment from all available data. This process substantially reduced the proportion of missing data at all sites except the plantar arch where, as noted above, views of the forefoot were available for 176 of 224 patients (78.6%) randomized to a BAP-first strategy and for 164 of 228 patients (71.9%) randomized to a BSX-first strategy. For the remaining 12 segments only, 1.2% of segments were missing. Preintervention angiograms were also classified according to the TASC II criteria for infrainguinal disease (Fig 1) by observers A and B, who did not confer and were unaware of the Bollinger scores, treatment(s) received, or patients' outcomes.[1]

Statistical methods. Summary measures for the Bollinger scores were derived after exploratory data analysis of the relationships between the scores at different segments. This was completed without reference to the randomized treatment. Interobserver agreement for the Bollinger and TASC II scores was assessed by calculating the percentage agreement from comparable categories. Differences in scores between categories were assessed by analyses of variance, and associations between categoric variables were assessed by χ^2 tests with Yates correction.

RESULTS

Preintervention angiograms were available and judged to be of sufficient quality to be scored using the Bollinger method for 418 patients (92.5%), and scores were available for 5229 of a possible 5434 arterial segments (96.2%) in those patients. Most of the missing data related to the plantar arch, where missing or suboptimal forefoot views made scoring problematic. Bollinger scores by individual segment in the trial cohort as a whole are reported in Table II and Fig 2.

As might have been expected, the profunda femoris artery was relatively spared, and most of the disease was concentrated in the distal SFA and proximal PA on either side of the adductor hiatus, where most patients had occlusive disease. With regard to infrapopliteal disease, the most severely diseased artery was the PTA, where the proximal or distal half was occluded in approximately one-half of patients. The ATA appeared less affected, with distal or proximal occlusions, or both, in approximately one-third of patients. The PerA was relatively spared; in almost one-half of patients, the PerA was essentially disease-free (at least lumenographically) in the proximal or distal half (compared with less than one-quarter of PTAs and less than one-third of ATAs). Where forefoot views were available, the plantar arch was considered occluded in almost 20% of cases.

Correlations between Bollinger scores in the 13 different arterial segments are reported in Table III. The strongest positive relationships were between disease in the proximal and distal SFA, distal PA, and the TPT, TPT and proximal PTA and PerA, and between the proximal and distal halves of the three crural vessels (PTA, ATA, and PerA). There were also some negative correlations; for example, increasing severity of disease in the SFA was associated with decreasing severity of disease in the PA/TPT segment, and vice versa.

Clinical sense and these exploratory analyses led to the decision to summarize the Bollinger scores as follows for the purposes of further analysis:

- Mean overall (whole leg) Bollinger score, calculated from the 12 segments omitting the plantar arch
- Mean above knee Bollinger score for the 4 above knee segments, where the major contribution is from the SFA
- Mean below knee Bollinger score for the 8 below knee segments, where the major contribution is from the crural arteries

In each case, the scores for the segments that could not be assessed were imputed as the mean of the segments that were scored for that patient. Because only a small proportion of data were missing, the results were not sensitive to this imputation choice.

To try to quantify the degree of interobserver variability associated with the angiographic scoring methods used in the study, we compared the original Bollinger scores provided by the first two Bollinger observers (observers 1 and 2) and the TASC II classifications provided by observers A and B. For the 358 cases where *both* observers had undertaken Bollinger scoring of *all* 12 segments (excluding the plantar arch), we calculated mean overall (whole leg), above knee, and below knee Bollinger scores for each observer in the manner described above. There were 396 angiograms considered adequate for TASC II classification by both observer A and B.

To compare inter-observer reliability for the two methods, Bollinger scores were placed into one of four groups (<3, 3-5, 6-8, ≥9) chosen to produce similar group sizes to those derived from the TASC II classification (classes A, B, C, and D). The percentages assigned to these Bollinger score groups and TASC II classes by observers 1 and 2 and by observers A and B, respectively, are reported in Table IV. There was no systematic bias between observers 1 and 2 with respect to whole leg, above knee, or below knee

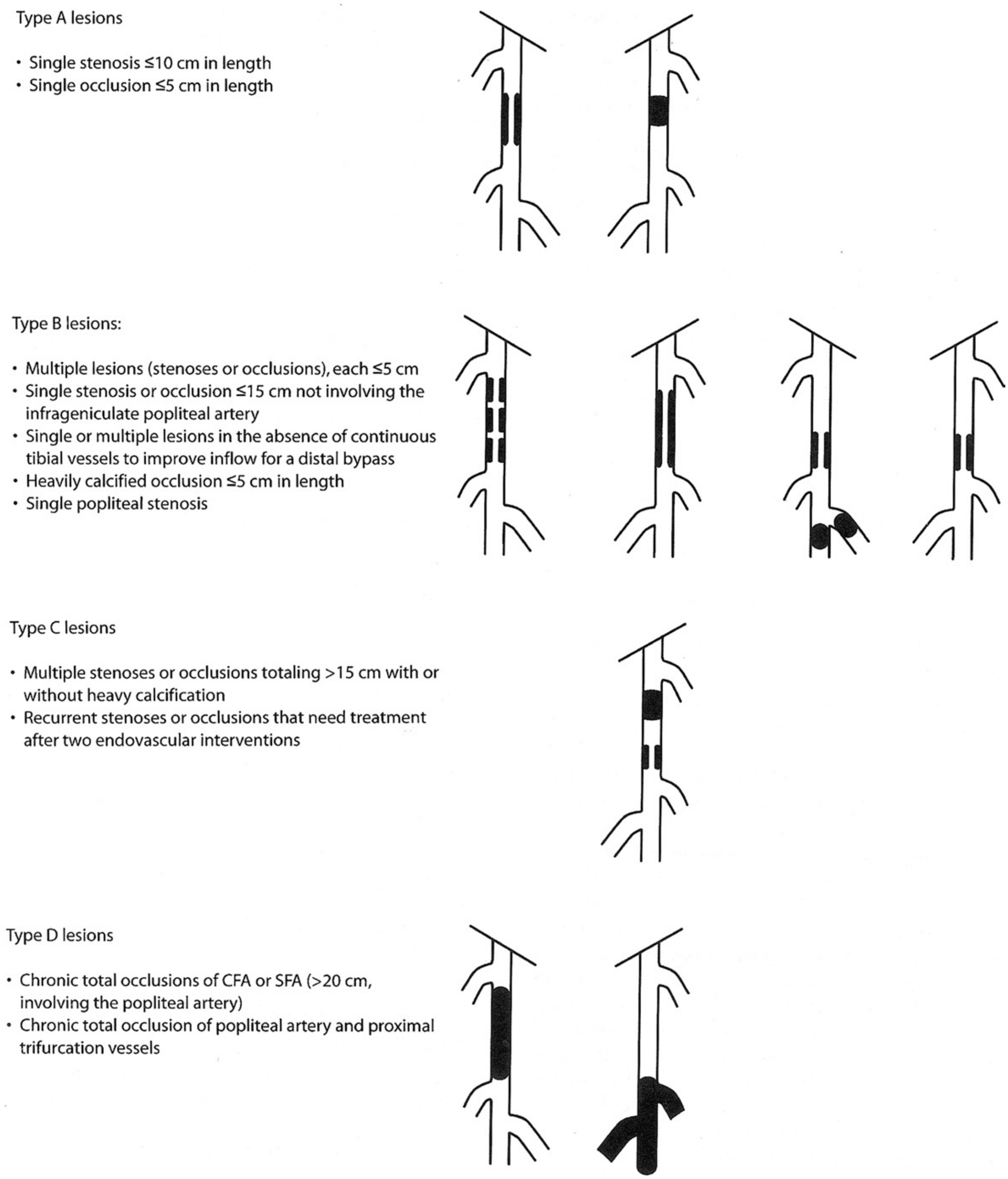

Fig 1. TransAtlantic Inter-Society Consensus II classification. (Taken from Journal of Vascular Surgery 2007;45 Suppl S:S51.)

Bollinger scores (P = .55, .19, and .22, respectively); indeed, they were very similar. However, there was a clear bias between observers A and B with respect to TASC II classification (test for trend $P <$ .001). Thus, observer B considered the cohort to have materially worse angiographic disease than observer A, with this difference being apparent in all four TASC II classes.

Table V summarizes the differences between the observers for the Bollinger groups and the TASC II classes. In about 75% of patients, observers 1 and 2 both placed the patient in the same Bollinger score group, and in <1% of patients was the discrepancy greater than one Bollinger score group. By contrast, there was agreement with respect to TASC II class in just <50% of the patients

Table II. Severity and distribution of arterial disease in the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial cohort as a whole as quantified by the Bollinger scoring method

	Patients with different Bollinger scores by individual arterial segment, %												
Arterial segment	*0*	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*13*	*15*	*No.*
Profunda	44.4	9.7	15.9	4.6	9.4	3.9	4.6	0.7	0.2	0.2	3.6	2.7	414
Proximal SFA	13.4	4.1	11.3	12.7	5.8	6	9.6	5.5	3.1	0.2	6.7	21.6	417
Distal SFA	4.1	2.6	6.2	5	6.5	4.6	8.9	4.1	4.6	1	26.1	26.4	417
Proximal popliteal	11.8	6	10.3	10.8	10.6	4.8	6.7	2.4	1.9	0.2	12.0	22.5	417
Distal popliteal	42.5	3.6	13	7.9	7.5	3.1	4.8	1.4	0.5	. . .	7.2	8.4	416
Tibioperoneal	54.7	1.0	5.1	5.3	9.0	1.2	7.0	. . .	0.2	. . .	1.9	14.5	413
Proximal PT	22.5	1.4	3.1	2.7	8.5	2.4	8.0	0.7	. . .	. . .	7.7	43	414
Distal PT	24.8	0.2	1.7	3.2	5.2	2	2.9	0.2	0.2	0.2	8.6	50.6	407
Proximal AT	26.6	1.4	4.3	3.4	11.6	3.9	5.8	1.9	0.2	. . .	10.6	30.2	414
Distal AT	37.6	0.7	2.2	2.2	4.5	3.7	3.2	0.2	0.2	. . .	7.7	37.6	404
Proximal peroneal	45.4	0.7	4.8	1.9	11.4	4.8	7.2	. . .	. . .	. . .	9.9	13.8	414
Distal peroneal	57.0	0.5	2	2.7	5.9	2.0	4.9	. . .	. . .	. . .	6.4	18.5	405
Plantar arch	12.1	. . .	. . .	. . .	14.1	. . .	54.4	. . .	. . .	. . .	.	19.4	340

AT, Anterior tibial; *PT*, posterior tibial; *SFA*, superficial femoral artery.

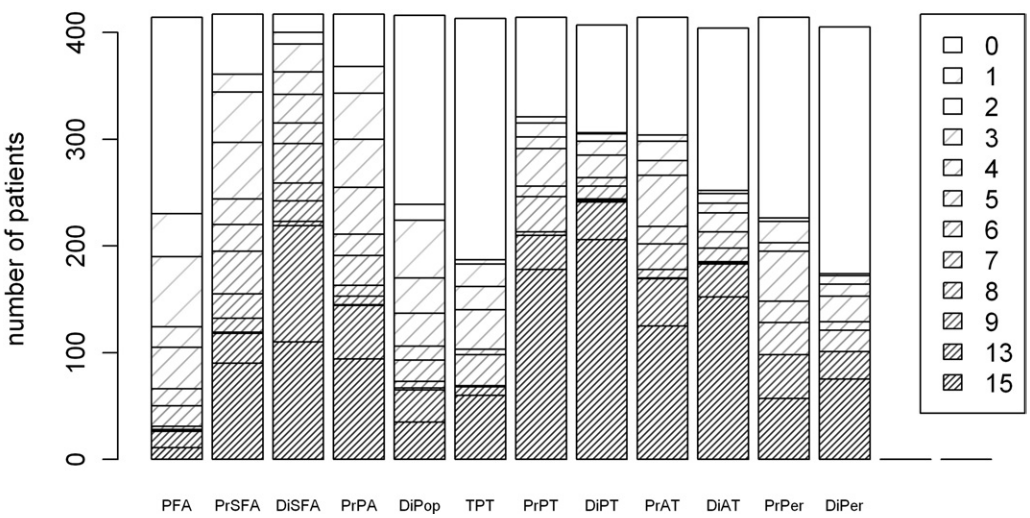

Fig 2. Distribution of Bollinger scores (0 to 15) in each arterial segment (plantar arch excluded). The proportions of each segment occluded are shown with the heaviest shading at the bottom of each bar, partially affected segments have intermediate shading, and the proportions unaffected in each bar are shown unshaded at the top of each bar. *PFA*, Profunda femoris; *Pr-SFA*, *Di-SFA*, proximal and distal superficial femoral; *Pr-PA*, *Di-PA*, proximal (above knee) and distal (below knee); *TPT*, tibioperoneal trunk; *Pr-PT*, *Di-PT*, proximal (upper half calf) and distal (lower half calf) posterior tibial; *Pr-AT*, *Di-AT*, proximal and distal anterior tibial; *Pr-Per*, *Di-Per*, proximal and distal peroneal.

and a discrepancy greater than one TASC class in just >10% of patients.

As was to be hoped and expected from the randomization process, the anatomic (angiographic) pattern of disease in the two trial arms was very similar in terms of individual arterial segments (Table VI) and whole leg, above knee and below knee aggregate Bollinger scores (Table VII). The two arms were also very similar in terms of the distribution of TASC II classes; data from observer A, who scored the disease less severely than observer B, are reported in Table VII.

The relationship between the total Bollinger score and the TASC II score is reported in Table VIII. Although the TASC II and Bollinger scores are generally related, as might have been expected given their different scope and methodologies, there are also many cases where they disagree. Examination of the details of the cases where there were the greatest discrepancies helped to explain the reasons for the differences between the TASC II and Bollinger scores. The TASC II scores do not take into account the extent of the disease in the more distal segments, specifically in the tibial arteries. Cases with a high Bollinger score but a relatively favorable TASC II classification of A or B were those where the largest burden of disease was in the more distal segments. The opposite case, when a TASC II D classification was matched with a low Bollinger score, was

Table III. Correlations (×100) between patients' Bollinger scores at different arterial segments

	Profunda	*Prox SFA*	*Distal SFA*	*Prox PA*	*Distal PA*	*Tib-Per*	*Prox PT*	*Distal PT*	*Prox AT*	*Distal AT*	*Prox Per*	*Distal Per*	*Plantar arch*
Profunda		11	−1	−6	7	13	15	14	13	11	13	7	6
Prox SFA	11		57	−22	−31	−25	−9	−4	−7	−3	−13	−4	3
Distal SFA	−1	57		−12	−28	−20	−16	−14	−9	−10	−16	−5	−11
Prox PA	−6	−22	−12		18	−2	2	−3	−1	2	6	−4	−3
Distal PA	7	−31	−28	18		41	25	13	19	5	20	13	−0
Tib-Per	13	−25	−20	−2	41		40	25	19	7	49	23	13
Prox PT	15	−9	−16	−2	25	40		78	23	11	24	−4	22
Distal PT	14	−4	−14	−3	13	25	78		12	6	14	−4	33
Prox AT	13	−7	−9	−1	19	19	23	12		73	9	−6	10
Distal AT	11	−3	−10	2	5	7	11	6	73		−0	−7	16
Prox Per	13	−13	−16	−6	20	49	24	14	9	−0		54	13
Distal Per	7	−4	−5	−4	13	23	−4	−4	−6	−7	54		4
Plantar arch	6	3	−11	−3	−0	13	22	33	10	16	13	4	

Shaded boxes denote significant correlations ($P < .05$).
AT, Anterior tibial; *PA,* popliteal artery; *Per,* peroneal; *PT,* posterior tibial; *SFA,* superficial femoral artery; *Tib-Per,* tibioperoneal.

Table IV. A comparison of Bollinger scores from observers 1 and 2 and of TransAtlantic Inter-Society Consensus (TASC) II classifications from observers A and B

	Bollinger scores, % in each group (n = 358)							*TASC II classes, % in each group (n = 396)*	
	Mean overall (whole leg) score		*Mean above knee score*		*Mean below knee score*				
	Observer		*Observer*		*Observer*			*Observer*	
	1	*2*	*1*	*2*	*1*	*2*		*A*	*B*
<3	7.3	4.5	10.3	11.2	16.5	16.2	A	15.7	2.8
3-5	39.4	39.1	37.2	41.6	32.4	27.9	B	41.9	30.1
6-8	43.0	48.0	38.3	35.2	31.8	32.4	C	29.8	46.5
≥9	10.3	8.4	14.2	12.0	19.3	23.5	D	12.6	20.7

Scorers 1 and 2 were consultant vascular interventional radiologists who independently assessed the preintervention angiograms according to the Bollinger scoring system, and scorers A and B were consultant vascular surgeons who independently assessed the preintervention angiograms according to the TASC II classification. None of the four assessors had knowledge of the treatment subsequently received or patient outcomes. Only patients with complete data from both observers (Bollinger, n = 358; TASC, n = 396) are included.

where extensive more proximal disease met the advanced TASC II criteria but where very little disease was found in the more distal segments. Thus, the Bollinger method appears to provide a fuller description of the disease characteristics of the patient with SLI due to multilevel (distal) disease than does the TASC II classification, which focuses largely on the femoropopliteal segment.

Table IX reports the mean whole leg, above knee, and below knee consensus Bollinger scores for five approximately equally-sized groups created following ranking of patients by increasing overall (whole leg without plantar arch) consensus Bollinger score. One can see that the below knee Bollinger score increases more rapidly than the above knee Bollinger scores as the overall severity of disease worsens. Thus, as described above, the disease in patients with the least overall burden of infrainguinal disease tends to be concentrated above the knee, but as the overall disease burden increases, all three—but especially the PTA and ATA—become increasingly involved in addition to the more proximal disease (Fig 3).

BASIL patients with critical limb ischemia (CLI), comprising 24% of the cohort with scorable angiograms, were a subgroup of SLI defined by a highest ankle pressure <50 mm Hg. They did not have significantly worse (higher) overall, above knee, or below knee Bollinger scores than those SLI patients with a highest ankle pressure of ≥50 mm Hg (Table IX). However, those BASIL patients who presented with tissue loss (68% of the cohort with scorable angiograms) had significantly worse (higher) overall and below knee, but not above knee, Bollinger scores than those patients who presented with only ischemic rest pain.

More generally, a highly significant negative correlation was found between mean above knee and below knee Bollinger scores (Pearson correlation = −0.14; $P = .005$). This finding is explored further in Table X, which summarizes the observed and expected numbers in a cross-tabulation of above knee and below knee Bollinger scores. The expected numbers are calculated for the case when there is

Table V. Difference between observers for Bollinger scores (observer 2 compared with observer 1) and TransAtlantic Inter-Society Consensus II (TASC) classification (observer B compared with observer A)

	Percentage of patients by differences in Bollinger group/TASC II class assigned by two observers					
Score	*Two or more groups/classes difference (lower)*	*One group/class difference (lower)*	*Same group/class both observers*	*One group/class difference (higher)*	*Two or more groups/classes difference (higher)*	*All*
Bollinger scores (n = 358)						
Total (whole leg)	0.28	7.26	75.42	24.30	0.28	100
Below knee	0.28	18.16	71.51	27.93	0.56	100
Above knee	0.00	10.61	74.86	25.14	0.00	100
TASC II classification (n = 396)	1.26	6.82	46.97	35.86	9.09	100

Scorers 1 and 2 were consultant vascular interventional radiologists who independently assessed the pre-intervention angiograms according to the Bollinger scoring system and scorers A and B were consultant vascular surgeons who independently assessed the pre-intervention angiograms according to the TASC II classification. None of the four assessors had knowledge of the treatment subsequently received or the patients' outcomes. Only cases with complete data from both observers (Bollinger, n = 358; TASC, n = 396) are included.

Table VI. Comparison of Bollinger scores by randomized groups by arterial segment

	BAP first (n = 224)		*BSX first (n = 228)*	
Mean Bollinger score	*No.*	*Mean (SD)*	*No.*	*Mean (SD)*
All sites	208	6.19 (2.23)	210	6.23 (2.22)
Profunda	208	2.53 (3.82)	206	2.18 (3.23)
Proximal SFA	208	6.77 (5.44)	209	6.27 (5.49)
Distal SFA	207	9.64 (5.14)	210	9.19 (5.21)
Proximal popliteal	207	6.90 (5.65)	210	6.98 (5.72)
Distal popliteal	207	3.86 (5.00)	209	3.37 (4.82)
Tibioperoneal trunk	207	3.61 (5.44)	206	3.51 (5.23)
Proximal PTA	207	8.65 (6.54)	207	8.55 (6.36)
Distal PTA	207	9.29 (6.67)	200	9.49 (6.56)
Proximal ATA	207	7.14 (6.24)	207	7.40 (6.36)
Distal ATA	206	7.18 (6.81)	198	7.54 (6.92)
Proximal PerA	207	4.49 (5.71)	207	4.80 (5.65)
Distal PerA	206	3.99 (5.99)	199	4.76 (6.18)
Plantar arch	176	6.38 (4.32)	164	7.13 (4.64)

ATA, Anterior tibial artery; *BAP,* balloon angioplasty; *BSX,* bypass surgery; *PerA,* peroneal artery; *PTA,* posterior tibial artery; *SD,* standard deviation; *SFA,* superficial femoral artery.

no association between the two scores. The observed/expected ratio of 0.796 is furthest from 1.0 for the group with the lowest above knee and below knee scores, suggesting that this negative correlation may be because patients with low scores for both upper and lower leg would not have been included in the study.

DISCUSSION

Reasons for scoring the trial angiograms. When designing the BASIL trial, the investigators and participants believed it was important to be able to describe the anatomic or at least the angiographic ("lumenographic")[8] severity and extent of disease in randomized patients for a number of reasons. Firstly, we wished to be able to establish that patients in the two arms were anatomically (angiographically) comparable. Secondly, given the unique nature of the trial, we believed it was especially important to facilitate generalization of the trial data to other groups of patients affected by similar anatomic (angiographic) patterns of disease; and, as an important corollary, not to those patients with different types of clinical and anatomic disease. Thirdly, we wished to explore the extent to which anatomic (angiographic) patterns of disease might predict outcomes (AFS, OS) for the BASIL cohort as a whole[5]; and, fourthly, whether it might be possible to predict likely success or failure of BSX and BAP on the basis the angiographic severity of disease.

To these ends, the 27 participating centers were asked to forward copies of preintervention imaging, which in almost all patients was intra-arterial digital subtraction angiography, for independent, blinded, batch analysis at the trial center. In this report we address aims one and two set out above by presenting an analysis of those angiograms using the Bollinger scoring method. The relationship between the pattern and severity of disease and overall survival (aim 3) has been reported elsewhere.[5] Aim four is not the subject of the present article but is the subject of on-going further analysis using different methodologies and tools.[9-19]

The angiographic characteristics of the BASIL trial patients. When BASIL trial results are considered, it is very important to remember that BASIL is emphatically not a trial of all patients with SLI, of which patients with CLI defined by an ankle pressure <50 mm Hg are a subgroup, any more than other vascular randomized controlled trials have, for example, been a study of all aneurysms or all carotid artery disease or all claudicant patients. Rather, BASIL was a trial of those SLI patients whose disease was due to infrainguinal disease, who were considered to require immediate or early revascularization, and in whom the responsible surgeons and interventionalists determined there was a "gray area of equipoise" for the best manner in which to achieve that revascularization.[20,21] Specifically, patients were only eligible for randomization in BASIL if there was true uncertainty about whether a BSX-first or BAP-first revascularization strategy was in the patient's best interests. As previously reported, this group comprised about one-third of the patients presenting to participating hospitals with SLI due to infrainguinal disease, and about 70% of those eligible patients were randomized.[2]

Table VII. Mean consensus Bollinger scores (above knee, below knee, and whole leg) and TransAtlantic Inter-Society Consensus (TASC) II classification (observer A) by randomized treatment

	Randomized treatment		
Scoring method	*BAP first (n = 224)*	*BSX first (n = 228)*	*Total*
Bollinger scores available, No.	208	210	
	Mean (SD)		
All 12 segments (whole leg less plantar arch)	6.31 (2.13)	6.20 (2.20)	
Above knee segments (4)	6.28 (2.63)	5.95 (2.61)	
Below knee segment (8)	6.32 (3.17)	6.32 (3.15)	
	No. per category (% of total)		*Total*
TASC II classification by observer A			
Not available	18 (8.03)	21 (9.21)	39
A	3 (1.34)	9 (3.95)	12
B	55 (24.55)	67 (29.39)	122
C	93 (41.50)	93 (40.79)	186
D	55 (24.55)	38 (16.67)	93
Total	224	228	452

BAP, balloon angioplasty; *BSX,* bypass surgery; *SD,* standard deviation.
Data based on consensus Bollinger scores and TASC II classifications from observer A.

Table VIII. The relationship between whole leg Bollinger scoring and TransAtlantic Inter-Society Consensus (TASC) II classification

	Mean Bollinger whole leg score[a]				
TASC	*0-4.5*	*4.5-6*	*6-8*	*8+*	*All*
TASC-A	4	5	2	1	12
TASC-B	36	26	46	14	122
TASC-C	44	45	50	45	184
TASC-D	8	16	29	40	93
All	92	92	127	100	418

[a]Data are based on consensus Bollinger scores (excluding the plantar arch) and TASC II classifications from observer A.

Table IX. Bollinger scores by increasing overall angiographic severity of disease, ankle pressure, and clinical presentation

		Score, mean (SD)		
Variable	*No.*	*Overall whole leg*	*Below knee*	*Above knee*
Bollinger score	418			
Group 1	83	3.03 (0.78)	1.57 (1.36)	5.97 (2.34)
Group 2	83	4.78 (0.37)	4.38 (1.25)	5.59 (2.44)
Group 3	84	6.13 (0.42)	6.13 (1.47)	6.14 (2.54)
Group 4	84	7.44 (0.37)	8.03 (1.30)	6.25 (2.49)
Group 5	84	9.35 (1.09)	10.21 (2.14)	7.62 (3.08)
Ankle pressure				
<50 mm Hg	101	6.21 (2.30)	6.13 (3.40)	6.37 (2.74)
≥50 mm Hg	317	5.99 (2.22)	5.91 (3.22)	6.16 (2.47)
P for difference		.40	.55	.49
Tissue loss				
Yes	286	6.56 (2.32)	6.46 (3.39)	6.75 (2.71)
No (rest pain only)	132	5.97 (2.24)	5.90 (3.33)	6.12 (2.64)
P for difference		.01	.02	.11

Data based on consensus Bollinger scores.

The Delphi consensus studies that preceded the trial[20,21] suggested that at the commencement of the trial, many UK vascular units were largely offering BAP in preference to BSX to SLI patients at the "good" end of anatomic and clinical SLI disease spectrum. Those SLI patients with the most severe, especially distal, disease were largely being offered femorodistal BSX rather than BAP. So in a trial that compared a BSX-first with a BAP-first revascularization strategy in patients thought to be equally suitable for both, it was highly likely that the type of BSX undertaken was going to be less "distal" overall than the totality of surgery undertaken for SLI and CLI. Similarly, the extent and complexity of the BAP undertaken in BASIL was likely to be significantly greater than commonly reported in patients being treated for disabling claudication. The present data lend general support to these presumptions, although further work is underway to determine if and how the nature of the BSX and BAP undertaken in BASIL changed during the recruitment period.

Analysis of the Bollinger scores shows that the two trial arms were very well matched and that in BASIL patients with the least overall burden of disease, the disease tends to be concentrated in the SFA and popliteal artery. However, as the overall severity of disease increases, the below knee arteries become increasingly diseased: the PT was the worst affected crural artery, and the peroneal appeared relatively spared. Interestingly, but perhaps not surprisingly given the above considerations, there was a significant negative correlation between mean above knee and the mean below knee Bollinger scores. Thus, most BASIL patients had severe disease either above or below the knee.

As suggested above, it appears likely that patients with mild to moderate disease above and below the knee were

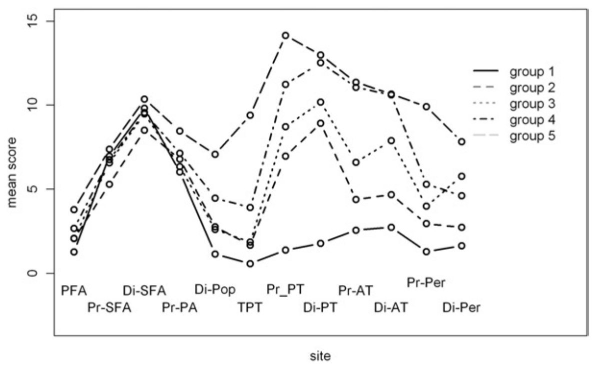

Fig 3. Pattern of disease by five groups according to groups by overall Bollinger mean score from 1 (best) to 5 (worst). *Di-AT,* Distal anterior tibial; *Di-PA,* distal (below knee) popliteal artery; *Di-Per,* distal peroneal; *Di-PT,* distal (lower half calf) posterior tibial; *Di-SFA,* distal superficial femoral artery; *PFA,* profunda femoris; *Pr-AT,* proximal anterior tibial.

Table X. Comparison of above knee and below knee Bollinger scores (number of cases and ratio of observed number to the expected number in the case where the two scores are unrelated)

Mean above knee Bollinger score	*No. of cases (observed to expected ratio)*[a] *Mean below knee Bollinger score*			
	<5	*5-8*	*≥8*	*Total*
≤5	37 (0.796)	42 (1.017)	66 (1.153)	145
5-8	56 (1.065)	51 (1.092)	57 (0.880)	164
≥8	41 (1.173)	26 (0.838)	42 (0.976)	109
Total	134	119	165	418

[a]Expected numbers are calculated from the marginal totals, assuming the two scores are independent. Data based on consensus Bollinger scores.

not considered eligible for randomization in BASIL because their disease was not severe enough to cause SLI or because they were considered best treated by BAP (no clinical equipoise). Similarly, it appears that patients with the severest disease above *and* below the knee were less likely to be eligible for randomization because they tended to be considered by the responsible vascular teams as best treated by BSX (again, no clinical equipoise). It is clearly very important that these considerations and the patterns of disease described here are kept in mind when interpreting the results of the BASIL trial, especially when trying to extrapolate the recommendations to other groups of SLI patients. The angiographic data presented here are reflected in the BSX and BAP procedures undertaken in BASIL, which are reported in detail elsewhere.[6]

The reviewers have criticized the lack of foot views of sufficient quality to allow reliable scoring of the plantar arch. We agree that best current practice involves the generation of such images and that the inclusion of plantar arch data in various runoff scores may add predictive value, although this was not the subject of the present report. However, in the population of patients considered by participants as eligible for randomization in BASIL where suitability for angioplasty was a sine qua non, for the reasons suggested above, plantar arch data may not have been as informative as in the entire population of SLI and CLI patients.

Choice of scoring systems. Various angiographic and runoff scoring systems have been described, and each has different characteristics, strengths, weakness, and purposes.[1,5,7,9-12,16] As discussed above, the purpose of the present study was to describe the angiographic patterns of disease in the BASIL cohort as a whole and in the two arms separately. The purpose was not to try to relate procedural (BSX or BAP) outcomes to the anatomic severity and extent of disease or, specifically runoff; those analyses are ongoing and will be the subject of a further separate report in due course.

The investigators and participants agreed at the outset of the trial (late 1990s) that the Bollinger scoring system would be used to describe the extent and severity of disease in the BASIL patients because it appeared to be reasonably user-friendly while at the same time offering considerable detail throughout the infrainguinal arterial tree. The TASC II classification did not exist at that time, but in response to subsequent requests from clinicians who use and value the TASC system, we have reported here the TASC II classification of the BASIL cohort. However, we have chosen not to make more extensive use of the TASC II classification when reporting the BASIL trial because, as present data show, it has significant limitations in this patient group.[1] The substantial and highly clinically significant systematic bias we found between the two observers who independently scored the angiograms using the TASC II method requires further investigation and generalization to further observers, and this work is on-going.

We have chosen not to emphasize or analyze statistically a direct comparison between the Bollinger scoring system and the TASC II classification because we think they are so different in method, scope, and purpose that it would be potentially misleading to do so. TASC II largely restricts itself to the aortoiliac and femoropopliteal segments. All of the BASIL patients had to have adequate inflow to support an infrainguinal bypass graft or angioplasty before randomization, and almost all the BASIL patients had significant infrapopliteal disease. Discriminating between SLI patients with different extents and severities of infrapopliteal artery disease appears likely to be important in predicting the success of, and thus the suitability for, different treatments. Indeed, we have already shown and reported elsewhere that the extent and severity of distal disease, according to Bollinger, is a very powerful predictor of overall outcome.[6]

The TASC II classification, by not permitting a full description of infrapopliteal disease, gives a less complete assessment of the type of patient entered into the BASIL trial. Perhaps not surprisingly, therefore, exploratory analyses have shown only a weak relationship between Bollinger scores and TASC II group in the BASIL cohort. In particular, patients can have quite severe infrainguinal disease in terms of overall Bollinger score but still be classified as a

TASC A or B because the TASC II assessment does not take in to account significant crural artery disease.

Furthermore, as described above, unlike Bollinger, which appears reproducible, the assessment of BASIL-like patients by means of TASC II appears to be associated with a high degree of interobserver error, which is the subject of further on-going studies. We understand that the TASC document and classification is currently undergoing further modifications (personal communication by Professor Lars Norgen) and it may be that any future "TASC III" classification of disease will deal with some of these issues. If so, it may be appropriate to compare the utility of Bollinger and a new TASC III classification in due course.

Compared with the TASC II scores, there was fairly good agreement between observers for the Bollinger scores, and differences could be resolved by a consensus from further independent scorers. The Bollinger scores were significantly higher in those with tissue loss than in those without, with the difference being greatest for the below knee score and not quite reaching a formal level of significance for the above knee score. However, those BASIL patients with what some might term "true" CLI, as defined by an ankle pressure <50 mm Hg, did not have worse disease as defined by whole leg, above knee, or below knee Bollinger scores than those who presented with ankle pressure >50 mm Hg. This finding may cast further doubt on the usefulness and appropriateness of an arbitrary ankle pressure cutoff as part of the international definition of limb-threatening chronic leg ischemia.[1-3,5,6]

CONCLUSIONS

Anatomic (angiographic) disease description in SLI patients requires a scoring system that is sensitive to differences in both femoropopliteal and infra-trifurcation artery disease. The Bollinger system appears well suited for this purpose, with practice becomes easy to use, and is associated with acceptably low levels of interobserver error. The below knee Bollinger score appears to discriminate better between individuals than does the above knee score. The TASC II classification appears to have significant limitations in this patient group due to lack of reproducibility and definition of crural disease. As was to be expected from the randomization process, the present analysis confirms that the patients in the two arms of the BASIL trial were well matched in terms of anatomic (angiographic) patterns of disease as determined by Bollinger scores and TASC II classification. The BASIL investigators and participants hope that the detailed angiographic analysis presented here will facilitate appropriate generalization of the trial data to other groups of patients affected by similar anatomic (angiographic) patterns of disease while helping to prevent inappropriate generalization to patients who are materially clinically and angiographically different.

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APPENDIX

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Data Monitoring Committee: Professor G. D. O. Lowe (Chairman), Professor R. M. Greenhalgh, Dr A. Nicholson, Professor R. Prescott (Professor R. J. Prescott and Dr A. Lee prepared the data for the committee).

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The following consultant vascular surgeons and interventional radiologists working at the following centers entered patients into the trial: (number in brackets indicates number of patients entered into BASIL) (*denotes took part in the BASIL audit): P. Bachoo, J. Brittenden, G. Cooper, S. Cross, J. Engeset, J. Hussey, E. Macauley, P. Thorpe, *Aberdeen Royal Infirmary (58); G. Stewart, K. Osbourne, Ayr Hospital (1); J. Moss, P. Nicholl, S. Silverman, J. Wingate, City Hospital, Birmingham (9); D. Adam, B. Balasubramanian, A. Bradbury, P. Crowe, J. Ferrando, M. Gannon, M. Henderson, K. Makhdoomi, D. Mosquera, T. Wilmink, *Heart of England NHS. Foundation Trust (33); T. Buckenham, R. Chalmers, R. Dawson, S. Fraser, I. Gillespie, S. Ingram, A. Jenkins, J. Murie, Z. Raza, Edinburgh Royal Infirmary (27); N. Jones, D. Lambert, T. Lees, R. Owen, J. Rose, G. Stansby, M. Wyatt, *Freeman Hospital, Newcastle (21); D. Byrne, R. Edwards, A. MacKay, J. Moss, R. Quin, P. Rogers, Gartnavel Hospital, Glasgow (23); D. Gilmour, D. Leiberman, D. McCarter, A. Reid, Glasgow Royal Infirmary (1); S. Dodds, M. Cleesby, A. Jewkes, B. Jones, C. Nelson, A. Parnell, Good Hope Hospital, Sutton Coldfield (11); P. Bell, A. Bolia, Leicester Royal Infirmary (1); N. Chalmers, I. Mohan, V. Smyth, M. Walker, Manchester Royal Infirmary (6); M. Collins, A. Garnham, G. Mackie, New Cross Hospital, Wolverhampton (9); P. Stonebridge, J. Houston, Ninewells Hospital, Dundee (1); M. Armon, J. Clarke, J. Cockburn, J. Colin, S. Girling, S. Scott-Barrett, P. Wilson, Y. Wilson, *Norfolk & Norwich Hospital (60); J. Beard, T. Cleveland, P. Chan, P. Gaines, R. Lonsdale, J. Michaels, A. Nassif, R. Niar, J. Rochester, S. Thomas, R. Wood, *Northern General Hospital, Sheffield (64); A. Ashour, V. Bhattachary, A. Nudawi, G. Timmons, Queen Elizabeth Hospital, Gateshead (2); A. Howd, M. Fleet, H. Ireland, K. McBride, A. Milne, A. Turner, Queen Margaret Hospital, Dunfermline (21); G. Ferguson, M. Onwudike, R. Razzaq, J. Tuck, Royal Bolton Infirmary (5); D. Baker, G. Hamilton, F. Hyint, A. Platts, J. Tibballs, A. Watkinson, Royal Free Hospital, London (3); K. Choji, R. Grimley, A. Jayatunga, R. Patel, J. Renny, S. Shiralkar, A. Wilinski, Russells Hall Hospital, Dudley (20); M. Alner, M. Duddy, A. Edwards, M. Simms, S. Smith, R. Vohra, Selly Oak Hospital, Birmingham (11); G. MacBain, R. Johnstone, G. Urquhart, G. Welch, Southern General Hospital, Glasgow (10); D. Durrans, B. Gwynn, C. Willard, Staffordshire General Hospital, Stafford (2); M. Thompson, R. Morgan, St Georges Hospital, London (3); J. Patel, J. Scott, I. Spark, St James Hospital, Leeds (2); K. Allen, A. Khan, J. Holland, Walsall Manor Hospital, Walsall (4); R. Ashleigh, S. Butterfield, R. England, C. McCollum, A. Nasim, M. Welch, *Wythenshawe Hospital, Manchester (44).

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